K092555

MAQUET

510(k) Summary

[as required by 21 CFR 807.92(c)]

DEC 2 3 2009

Submitter	**MAQUET Cardiopulmonary AG** Hechinger Strasse 38 72145 Hirrlingen Germany
Contact Person	Frank Moehrke Phone: 011 49 7478 921 229 Fax: 011 49 7478 921 400
Date Prepared	February 26, 2009
Device Trade Name	**PLEGIOX Cardioplegia Heat Exchanger with Softline Coating**
Common/Usual Name	Cardioplegia heat exchanger
Classification Names	Cardiopulmonary bypass heat exchanger *(21 CFR 870.4240 – Product Code: DTR)*
Legally Marketed Devices	- PLEGIOX Cardioplegia Heat Exchanger with and without Safeline Coating (K072583), - QUADROX-i Adult microporous membrane Oxygenator with and without integrated Arterial Filter with Softline Coating (K082117)

Device Description

The PLEGIOX is a cardioplegia heat exchanger with integrated bubble trap. It is delivered in a pyrogen-free and sterile status.

Indications for Use

The PLEGIOX Heat Exchanger is used to set and maintain the temperature (for given flow rates and within the given temperature range) of blood cardioplegic and crystalloid cardioplegic solutions during extracorporeal circulation.
The product is designed for single use only, for an application period of no longer than 6 hours.

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Statement of Technical Comparison

The PLEGIOX Cardioplegia Heat Exchanger with Softline Coating is identical to the PLEGIOX Cardioplegia Heat Exchanger with and without Safeline Coating with the only exception that the PLEGIOX Cardioplegia Heat Exchanger with Softline Coating has been coated with Softline Coating instead of Safeline Coating and no coating respectively. However, the Softline Coating is the same as with the QUADROX-i Adult microporous membrane Oxygenator with and without integrated Arterial Filter with Softline Coating. Besides this difference the PLEGIOX Cardioplegia Heat Exchanger with Softline Coating is the same in design, intended use, method of operation, components, packaging, and fundamental scientific technology as compared to the PLEGIOX Cardioplegia Heat Exchanger with and without Safeline Coating.

Determination of Substantial Equivalence

Evaluation on safety and effectiveness was executed to demonstrate that the PLEGIOX Cardioplegia Heat Exchanger with Softline Coating described in this submission is substantially equivalent to the PLEGIOX Cardioplegia Heat Exchanger with and without Safeline Coating as heat exchanger and to the QUADROX-i Adult microporous membrane Oxygenator with and without integrated Arterial Filter with Softline Coating regarding the Softline Coating.

The following areas have been tested and / or evaluated:

- Integrity
- Performance
- Biocompatibility
- Sterility

Conclusion

The data given demonstrate that the PLEGIOX Cardioplegia Heat Exchanger with Softline Coating is substantially equivalent to the named predicate devices which hold currently market clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 21 2010

Maquet Cardiopulmonary AG
c/o Mr. Frank Moehrke
Regulatory Affairs Manager
Hechinger Strasse 38
72145 Hirringen
Germany

Re: K090555
Maquet PLEGIOX Cardioplegia Heat Exchanger with Softline Coating
Regulation Number: 21 CFR 870.4240
Regulation Name: Heat-Exchanger, Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DTR
Dated: December 23, 2009

Dear Mr. Moehrke:

This letter corrects our substantially equivalent letter of December 23, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your

device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090555

Device Name:

PLEGIOX Cardioplegia Heat Exchanger with Softline Coating

Indications for Use:

The PLEGIOX Heat Exchanger is used to set and maintain the temperature (for given flow rates and within the given temperature range) of blood cardioplegic and crystalloid cardioplegic solutions during extracorporeal circulation.

The product is designed for single use only, for an application period of no longer than 6 hours.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090555